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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/441,857 11/18/99 DUFFY

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EXAMINER

HM22/0214

KENYON & KENYON
ONE BROADWAY
NEW YORK NY 10004

CANELLA, K.
ART UNIT

PAPER NUMBER

1642
DATE MAILED:

02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/441,857

Applicant(s)

Duffy et al

Examiner

Karen Canella

Group Art Unit

1642



- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1-80 is/are pending in the application.
- Of the above, claim(s) 5, 6, 13-17, 21-29, 31-33, 37-40, 42-54, 58-61, 63-69, and is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-4, 7-12, 18-20, 30, 34-36, 41, 55-57, 62, and 70 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1, 7
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Applicant's election of Invention I in Paper No.6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-80 are pending. Claims 5, 6, 13-17, 21-29, 31-33, 37-40, 42-54, 58-61, 63-69 and 71-80, drawn to non-elected inventions, are withdrawn from consideration. Claims 1-4, 7-12, 18-20, 30, 34-36, 41, 55-57, 62 and 70 are examined on the merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4, 7-12, 18-20, 30, 34-36, 41, 55-57, 62 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claims 1, 12, 18, 30, 34, 35, 41, 55, 56 and 62 recite "wth3". The claims are rejected as being indefinite in the use of wth3 as the only means of identifying the claimed polypeptides. The use of laboratory designations only to identify a particular polypeptide/polynucleotide renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct proteins and genes. Amendment of the claims to include a SEQ ID NO would more unambiguously define the claimed polynucleotides.

(B) Claim 4 recites "...and comprising at least three amino acid residues of SEQ ID NO:...". It is not stated that the residues should be contiguous. For purposes of examination the claim will be read as ---and comprising at least three contiguous amino acid residues of SEQ ID NO:---.

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5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 4 and 7-12, 18, 19, 30, 34-36, 41, 55-57 and 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic fragments consisting of SEQ ID NO:19-24 and the isolated nucleic acids of SEQ ID NO:7, 10 and 11 and polynucleotides encoding SEQ ID NO:12, does not reasonably provide enablement for additional immunogenic fragments derived from SEQ ID NO:12 and undisclosed polynucleotides which hybridize to SEQ ID NO:7, 10 and 11 or undisclosed polynucleotides which hybridize to the polynucleotides encoding SEQ ID NO:12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

(A)As drawn to immunogenic fragments of SEQ ID NO:12

Claims 4 and 7-12 are drawn to an isolated nucleic acid encoding an immunogenic fragment of wth3 having from 7-25 contiguous amino acid residues of SEQ ID NO:12 and comprising at least three contiguous amino acid residues of SEQ ID NO:19-24. The specification teaches SEQ ID NO:19-24 as immunogenic fragments of SEQ ID NO:12. One of skill in the art would not be able to anticipate additional fragments of SEQ ID NO:12 containing only three contiguous amino acid residues of SEQ ID NO:19-24 that would be immunogenic in a given host.

Paul (Fundamental Immunology, 3rd Edition, pg. 251, column 1, lines 11-12) states that immunogenicity is limited by self-tolerance, and that the repertoire of potential antigenic sites in a given polypeptide is a specific for the host organism. Klein ("Self-nonsel discrimination, histoincompatibility, and the concept of immunology", Immunogenetics, 1999, Vol. 50, No. 3-4, pp. 116-123) teaches that the property of immunogenicity for a polypeptide is based upon the

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recognition of said polypeptide as a "non-self" polypeptide. Ristori et al (FASEB, 2000, Vol. 14, No. 3, pp. 431-438) have disclosed that the discrimination between self and non-self proteins do not rely on simple qualitative features of the amino acid sequences in question, and that foreign, "non-self" peptides, known not to be present in humans, can mimic "self" antigens and thus can be tolerated (non-immunogenic) within the host. Therefore, it would be difficult to predict what peptides an "epitope" would consist of having only the amino acid sequence of the SEQ ID NO:12 polypeptide.

Paul also teaches (supra, pg. 249, column 2, lines 10-13) that to determine the immunogenicity of certain regions of a protein, knowledge of the three dimensional structure of the protein is required to determine which polypeptides in a given protein would be accessible on the surface of the protein in order for the putative antigenic determinant to be bound by the antibody. In addition, Paul states that mobility of the putative antigenic determinant within the native protein structure is also a determining factor for the binding of the antigenic determinant to an antibody. Paul points out (supra, pg. 250, lines 4-8) that "Measurement of the mobility in the native protein is largely dependent on the availability of a high resolution crystal structure, so its applicability is limited to only a small subset of proteins." The determination of an "immunogenic fragment" is clearly a non-trivial enterprise requiring undue experimentation for one of skill in the art.

(B) As drawn to isolated nucleic acids which hybridize to the claimed polynucleotides.

Claims 18, 19, 30, 34-36, 41, 55-57 and 62 are drawn to non-disclosed nucleic acids which hybridize to SEQ ID NO:10, and non-disclosed nucleic acids which hybridize to polynucleotides encoding wth3 under conditions wherein said polynucleotides fail to hybridize with RAB6. The exclusion of hybridization to RAB6, or the recitation of "stringent hybridization conditions" is not limiting. When given the broadest reasonable interpretation, the claims are clearly intended to encompass a variety of species including full-length cDNAs, genes and protein coding regions. Clearly, it would be expected that a substantial number of the hybridizing or

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complementary polynucleotides encompassed by the claims would not share either structural or functional properties with polynucleotides that encode SEQ ID NO:12 or encode proteins that share either structural or functional properties with wth3. The specification fails to provide an enabling disclosure for how one would use such non-disclosed polynucleotides. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art on how to use the broadly claimed species. For the above reasons, undue experimentation would be required to practice the claimed invention.

7. The polynucleotides of SEQ ID NO:7, 10, 11 and the polynucleotides encoding SEQ ID NO:12 are free of the art. The polynucleotides encoding polypeptides consisting of SEQ ID NO:19-24 are free of the art.


Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

February 12, 2001


ANTHONY G. CAPUTA
UNITED STATES PATENT EXAMINER
FBI ELECTRONIC CENTER 1000